



**DRAFT**

**PROTOCOL**

**Study Title:**

Characterization of Chlorinated Paraffin Oils

**Document Number:** 031533-0

**Data Requirement:**

40 CFR § 792.105, Test, Control, and Reference Substance Characterization

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**Study Sponsor:**

Qualice, LLC  
P.O. Box 1519  
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**Protocol:**

Characterization of Chlorinated Paraffin Oils

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**DISTRIBUTION**

**Original:**

Ricerca Biosciences, LLC Archives

**Copies:**

Ricerca Biosciences, LLC/Study Director/D. Keenan (1)  
Landis International/Sponsor Representative/D. Hattermann (2)  
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## INTRODUCTION

Chlorinated paraffin Oils are industrial chemicals used as lubricant additives and as flame retardants.

### ***STUDY TITLE***

Characterization of Chlorinated paraffin Oils

### ***STUDY NUMBER***

031533

### ***SPONSOR***

Qualice, LLC  
P.O. Box 1519  
11 E.V. Hogan Drive  
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### ***SPONSOR REPRESENTATIVE***

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### ***TESTING FACILITY***

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## PURPOSE

The purpose of this study is to determine the identity and purity of different chlorinated paraffin oils.

## JUSTIFICATION OF TEST SYSTEM

Not Applicable

## EXPERIMENTAL START AND TERMINATION DATES

The proposed experimental start and termination dates are projected to occur in October 2013.

### *SCHEDULE OF EVENTS*

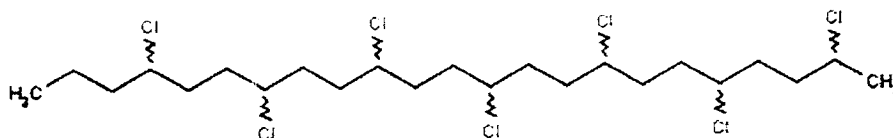
Proposed Study Initiation Date:	October 2013
Proposed Experimental Start Date:	October 2013
Proposed Experimental Completion Date:	November 2013
Proposed Study Completion Date:	November 2013

The actual dates will be listed in the draft and final report.

## MATERIALS

### *TEST SUBSTANCES*

- Chlorinated Paraffin Oils



Note: This is a general structure with chain length variations and potential branching

Common Name: Chlorinated Paraffin Oil

- Test Substance 1

CAS Number: 1417900-96-9  
Purity: Provided in draft and final report  
Chem. Abstr. Name: Alkanes, C<sub>21-34</sub> – branched and linear, chloro

- **Test Substance 2**

CAS Number: 1401974-24-0  
Purity: Provided in draft and final report  
Chem. Abstr. Name: Alkanes, C<sub>22-30</sub> – branched and linear, chloro

- **Test Substance 3**

CAS Number: 1402738-52-6  
Purity: Provided in draft and final report  
Chem. Abstr. Name: Alkanes, C<sub>24-28</sub> - chloro

All preparations of the test substances for analyses will be uniquely identified.

### ***STORAGE AND RETENTION***

The Sponsor or Sponsor Representative will supply the test substances for characterization. The test substances will be stored under conditions specified by the Sponsor or Sponsor Representative. Retention of the test substance is not required under 40 CFR TSCA Part 792.105, because experimental phase will be completed  $\leq$  four weeks, however, if the experimental phase does last more than four weeks, retention samples will be taken.

### ***CHARACTERIZATION***

The identity, strength, purity, and composition for the test substances are being determined in this study including, but not limited to, carbon content and percent chlorination for each test substance. The determination of the stability and solubility are outside the scope of this study.

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## **PROCEDURES**

The following detail is provided as a guideline for the conduct of the study. Good scientific judgment may be applied to optimize the experimental results. The Study Director will document all changes in, or revisions to, this approved protocol. The actual procedures will be recorded in the data and detailed in the draft and final report.

The following methods will be applied to the test substance:

CBI - 2

CBI - 3

Any changes made prior to or during analysis will be documented in the raw data and listed in the draft and final report.

## **METHODS TO CONTROL BIAS**

As applicable, bias will be controlled by ensuring:

- Each instrument is qualified for use.
- Each instrument is calibrated and maintained per SOP.
- At a minimum, duplicate preparations/injections will be made for purity determination.

## **PROPOSED STATISTICAL METHOD(S)**

All data will be collected by the instrumental software (validated systems). All calculations will be performed by Microsoft Excel<sup>TM</sup> (non-validated system) and will be peer verified for correctness. Additional statistical methods and/ or software systems may be used, as appropriate, and will be documented in the study file and listed in the draft and final report.

## **RECORDS TO BE MAINTAINED**

Analysts shall document all experimentation such that an experienced scientist can reconstruct the work. Documentation shall include sample identifications, weighings, dilutions, and calculations. Additional documentation shall include instrumentation and equipment utilized during the study, as well as documentation of prepared reagents and solutions.

All study data shall be verified and maintained in folders in the project activity file. Research notebook(s) shall be placed in the project activity file at the completion of the study. Other comments, descriptions, calculations, correspondence, and etc., shall be placed in the project activity file in memo form.

The original study protocol and protocol amendments, if necessary, originating from the study will be maintained by the Study Director until completion of the study, with a signed copy sent to the Sponsor Representative.

Upon conclusion of the study, a Certificate of Analysis and report shall be submitted to the Sponsor. An accurate study file, including original raw data, shall be submitted to the Ricerca Biosciences, LLC Archives, 7528 Auburn Road, Concord, Ohio and then transferred to the Sponsor for archiving.

## **GLP STATEMENT**

The described study will be conducted in accordance with the Good Laboratory Practice Standards, 40 TSCA Part 792.

## REPORT AND CERTIFICATE OF ANALYSIS

A Certificate of Analysis (COA) will be issued for each test substance. Before issuance, the draft COAs and supporting data will be audited by Quality Assurance. The COAs will be issued per Ricerca SOP.

A draft and final report will be prepared at the conclusion of the study. The report shall include, but not necessarily be limited to, the following:

- Name and address of the facility performing the study and the dates on which the study was initiated and completed, terminated, or discontinued.
- Reference(s) to, and/or a detailed description of, all methods used.
- A copy of each Certificate of Analysis.
- A summary and analysis of the data generated while conducting the study, and representative transformations, calculations or operations performed on the data.
- Identification of the test substances used in the study.
- All deviations and changes from the protocol.
- A description of all circumstances that may have affected the quality or integrity of the data.
- Name and signature of the Study Director, the names of other scientists or professionals, and the names of supervisory personnel involved in the study.
- Statistical methods employed for analyzing the data. A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.
- Locations where raw data and the final report are to be stored.
- The signed and dated statement by the Ricerca Quality Assurance Unit specifying the dates of study inspections and dates the findings were reported to the Study Director and Management, when applicable.
- The signed and dated statement by the Study Director describing compliance with the Good Laboratory Practice Standards as specified in 40 CFR Part 792.

## SAFETY AND HEALTH

- Laboratory personnel will practice good sanitation and health habits.
- Any health condition of laboratory personnel that may be considered to adversely affect the study will be reported to the Supervisor and Study Director.
- Any test substance related injury to lab personnel will be reported to the Supervisor and Study Director.
- Every reasonable precaution shall be taken to prevent inadvertent exposure of personnel and the environment to the test substance.

- The Sponsor will provide the Material Safety Data Sheet (MSDS) for the test substances used in the study. The MSDSs will be available to all personnel involved in the study. If an MSDS is not available, it is the responsibility of the Sponsor to provide all available safety-related information for distribution to personnel involved in the study.

## CHANGES TO THE PROTOCOL

All agreed upon amendments will be expressed in writing, signed and dated by the Sponsor Representative and the Study Director. Copies of the signed amendments will be returned to the Study Director and Sponsor's Representative and appended to the protocol.

Deviations from the protocol, if any, will be documented in the study file and listed in the draft and final report.

## PROTOCOL ACCEPTANCE

**Study Title:** Characterization of Chlorinated paraffin Oils

**Document Number:** 031533-0

**Testing Facility:** Ricerca Biosciences, LLC  
AgChem Product Development  
7528 Auburn Road  
Concord, OH 44077

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**Daniel J. Keenan, Study Director**  
Ricerca Biosciences, LLC

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**Date**

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**Phillip Cassidy, Management**  
Ricerca Biosciences, LLC

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**Date**

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**Dennis Hattermann, Ph.D., Sponsor Representative**  
Landis International, Inc.

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**Date**